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EXAMINER
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HOUSTON, ELIZABETH

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3731

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### ***Response to Arguments***

Applicant's arguments filed 09/09/10 have been fully considered but they are not persuasive. Applicant states that modifying Lashinski with the closed system of Lau would be improper because it does not permit the replenishment of fluid to maintain the temperature of the fluid as required by Lashinski. However, examiner sets forth that based on the teachings of Lashinski and Lau, it would not be unreasonable to modify the device based on the several options that are offered. Lashinski discloses various embodiments for heating the stent and balloon. For example, in figures 2, 5 and 7, the fluid is released at the distal end of the balloon in order to maintain temperature and pressure. In figure 3, fluid is released proximal of the balloon in order to be in contact with the stent. This provides an additional means for affecting the phase change of the stent in addition to the heat exchange with the balloon (C5:L7-16). In other words, release of the heated fluid at the distal end of the stent is not essential to the function of the device, as is asserted by applicant. Lau merely offers another alternative for heating the balloon and stent for expansion that does not require communication with the blood vessel lumen or the inner tube of the catheter. A person of ordinary skill has good reason to pursue the known options within his or her technical grasp if it yields predictable results.

With respect to the Stack reference, applicant argues that the structure of Stacks catheter is different from that of Lashinski (side by side lumens rather than coaxial) and thus one of skill would not look to Stack to modify Lashinski particularly since the bumpers provide an protrusion to compensate for the location of the inner lumen. Note that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Thus it would be well within the ordinary skill to determine how to incorporate the advantages of stent bumpers taught by Stack into the device of Lashinski.

With respect to Rabkin, applicant states that Rabkin requires an inflow and outflow channel in order to circulate the cool fluid which would not be capable in the closed system of modified Lashinski. However, examiner asserts that one of ordinary skill would recognize the necessary modifications of the device required in order to provide for the advantage of delivering cooling fluid. Again, the test for obviousness is not whether the features of a

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secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

With respect to Kasprzyk, applicant argues that the elements 50 and 51 are not supplying heat to any portion of the device, in particular to the immediate area surrounding the balloon since they are disposed within the balloon. Applicant goes on to state that the elements direct electrical power from the power source to the conductive layer (52), which happens to be part of the balloon. It is unclear how applicant can claim that elements 50 and 51 do not supply heat to any portion of the device when they are clearly supplying heat to a layer of the balloon. There is no claimed limitation that precludes the conducting elements 50 and 51 from being considered heating elements. Further, there is nothing in the claims that require the heating element supply heat to an area surrounding the balloon. In fact the claim requires that the balloon overlie the heating element which is positioned around the inner tube. In other words, the heating element is "within the balloon" as shown by the figures of instant invention. Applicant goes on to argue that Lashinski and Lau use inflation fluid as the heating element while Kasprzyk does not disclose supplying electrical current to the inflation fluid, but rather to a layer of the balloon. However, examiner does not suggest that the heating element of Kasprzyk would be used for heating the inflation fluid. Rather, examiner suggests that the heating element of Kasprzyk could be used as an alternative heating element.

/E. H./

Examiner, Art Unit 3731